REMARKS

Claim 1-17 are pending in the instant patent application. Claims 6, 9-14 and 16 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 1-5, 7, 8, 15 and 17 have been rejected. Claim 1 has been amended. Claim 17 has been canceled. New claim 18 has been added. Support for this amendment is provided in the specification at page 17 through page 16, line 30 and page 32, line 27 though page 33, line 14, Example 1 and claim 1, as filed. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement as set forth in the Communication mailed October 1, 2003. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 6, 9-14 and 16 without prejudice. Further, Applicants have amended the claims to be drawn to the elected sequence. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention lacks patentable utility. Further, these claims have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids for prostate malignancy detection.

Further, with respect to claim 17, the Examiner suggests that there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO:84 as a vaccine.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that the specification is unclear with respect to the source of tissue of the nucleic acid sequence of SEQ ID NO:84 and the level of expression of SEQ ID NO:84 in cancer vs. normal tissue. The instant specification states at page 117, lines 23 through 27 that a CLASP 2 marker such as SEQ ID NO:84 exhibits detectable expression **only** in cancer tissue

thus making clear the levels of expression in cancer vs. normal tissue. Further, it is stated that the sequence must exhibit specificity for the tumor tissue or interest, which in this case, as made clear throughout the rest of the specification is prostate cancer tissue. Accordingly, the Examiner's basis for the rejection of claims 1-5, 7, 8, 15 is flawed.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:84 as having detectable expression only in prostate cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for prostate cancer, thus satisfying the utility requirement.

Applicants have canceled claim 17 this mooting rejections relating to this claim.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is respectfully requested in light of the claim amendments and the above remarks.

III. Rejection of Claim 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that the specification fails to provide descriptive support for the generic claim to "a nucleic acid that selectively hybridizes to the nucleic acid comprising SEQ ID NO:84". The Examiner also suggests that the large genus of nucleic acids having at least 60% sequence identity to SEQ ID NO:84 is not supported by the written description of the instant application.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence hybridizes under stringent conditions and have defined these conditions in accordance with teachings at page 14, line 17, through page 16, line 30. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 85% identity in accordance with teachings at page 32, line 27 though page 33, line 7. Further, in accordance the teachings of Example 1, Applicants have amended claim 1 to state that the nucleic acid molecule is detectably

expressed in prostate cancer tissue.

Detailed methodologies for ascertaining sequences which meet the structural and functional limitations of the instant amended claims are set forth in the specification at page 13, line 3, through page 14, line 16, and page 14, line 17 through page 16, line 30 and Example 1. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:84 and its expression in prostate tumor tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

IV. Rejection of Claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. § 102(a)

Claims 1, 2, 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 102(a) as being anticipated by a sequence with accession No. AK027241. The Examiner suggests that the sequence of accession no. AK027241 is 21.7% identical to SEQ ID NO:84, with bp 5 to 936 99.6% identical to bp 3259-4190 of SEQ ID NO:84. Thus, the Examiner suggests that the sequence with accession no. AK027241 will hybridize specifically to SEQ ID NO:84 in accordance with part (c) of claim 1. Further, the Examiner suggests that this human cDNA was cloned into a vector and must have been used in host cells.

Applicants respectfully traverse this rejection.

While the sequence of accession no. AK027241 may exhibit a region of similarity to SEQ ID NO:84, there are also regions of disparity and thus this sequence is different from the instant claimed invention. Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from this prior art sequence, Applicants have amended claim 1, part (c), to state that the nucleic acid molecule exhibits substantial sequence similarity to at least 300

nucleotides of the nucleic acid molecule of (a) or (b) and hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). Support for this amendment is provided in the specification at page 14, line 17, through page 16, line 30. The sequence of AK027241, with its regions of disparity would not hybridize under stringent conditions as now claimed.

Thus, this reference does not teach a sequence with all the elements of the claimed invention and cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

V. Rejection of Claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. § 102(b)

Claims 1, 2, 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by accession No. AF0123851. The Examiner suggests that accession No. AF0123851 discloses a sequence which shares 6.1% identity with SEQ ID NO:84 with bp 1 to 261 having 99.6% identity to bp 3695-3955 of SEQ ID NO:84. Thus, the Examiner suggests that the sequence with accession no.

AF0123851 will hybridize specifically to SEQ ID NO:84 as set forth in part (c) of claim 1. Further, the Examiner suggests that this human cDNA was cloned into a vector and that host cells were made.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from prior art teachings such as the sequence of accession no. AF0123851, Applicants have amended the claim 1, part (c), to state that a nucleic acid molecule exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid molecule of (a) or (b) and hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). further, Applicants have amended part (d) to clarify that the nucleic acid molecule has at least 85% sequence identity over the entire length to the nucleic acid molecule of (a) or (b) that hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). Support for these amendments is provided in the specification at page 14, line 17, through page 16, line 30 and page 33, lines 8-

14. The sequence of AF0123851 is different from the nucleic acid molecule as claimed.

Thus, this reference does not teach a sequence with all the elements of the claimed invention and cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

VI. Rejection of Claim 15 under 35 U.S.C. § 102(b)

Claim 15 has been rejected under 35 U.S.C. § 102(b) as being anticipated by GibcoBRL Catalog (p. 7-7, 1993-94). The Examiner suggests that this catalog teaches a kit with random primers which are suitable for DNA synthesis. Thus, the Examiner suggests that since any DNA can be amplified with such primers, they can be used to detect the nucleic acid comprising SEQ ID NO:84.

Applicants respectfully traverse this rejection.

MPEP §2131 is quite clear; to anticipate a claim the reference must teach all the elements of the claimed invention. Claim 15 is drawn to a kit for detecting a risk of cancer or presence of cancer in a patient. The kit comprises a means for determining the presence of a nucleic acid molecule comprising:

(a) a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 198; (b) nucleic acid sequence of SEQ ID NO:84; (c) a nucleic acid sequence that exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid molecule of (a) or (b) and hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b); or (d) a nucleic acid molecule having at least 85% sequence identity over the entire length of the nucleic acid molecule of (a) or (b). The vague teachings of the Gibco Catalog regarding a kit for random primer generation in no way teaches a means for detection of these specific nucleic acid molecules.

Thus, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: March 9, 2004

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